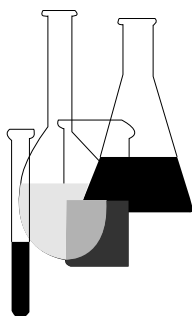




Product Properties Test Guidelines

OPPTS 830.1800 Enforcement Analytical Method



“Public Draft”

INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

Public Draft Access Information: This draft guideline is part of a series of related harmonized guidelines that need to be considered as a unit. *For copies:* These guidelines are available electronically from the EPA Public Access Gopher (gopher.epa.gov) under the heading “Environmental Test Methods and Guidelines” or in paper by contacting the OPP Public Docket at (703) 305-5805 or by e-mail: guidelines@epamail.epa.gov.

To Submit Comments: Interested persons are invited to submit comments. By mail: Public Docket and Freedom of Information Section, Office of Pesticide Programs, Field Operations Division (7506C), Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person: bring to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Comments may also be submitted electronically by sending electronic mail (e-mail) to: guidelines@epamail.epa.gov.

Final Guideline Release: This document is available from the U.S. Government Printing Office, Washington, DC 20402 on *The Federal Bulletin Board*. By modem dial 202-512-1387, telnet: federal.bbs.gpo.gov 3001, or call 202-512-1530 for disks or paper copies. This guideline is available in ASCII and PDF (portable document format).

OPPTS 830.1800 Enforcement analytical method.

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*) and the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is 40 CFR 158.180.

(b) **Information required.** An analytical method suitable for enforcement purposes must be provided for each active ingredient in the product and for each other ingredient or impurity that is determined to be toxicologically significant. Copies of these methods should be sent to: Chief, Analytical Chemistry Laboratory, BARC East, bldg. 306, Beltsville, MD 20705. Any new or changed samples should be sent to the same address.

(c) **Data reporting format.** (1) The manufacturer's/registrant's/petitioner's reports should include all information necessary to provide complete and accurate topical discussions of the pesticide product.

(i) *Title/cover page.* Title page and additional documentation requirements (i.e., requirements for data submission and procedures for claims of confidentiality of data) if relevant to the study report should precede the content of the study formatted below. These currently proposed requirements are described at 49 FR 37596, September 26, 1984.

(ii) *Table of contents.*

(A) *Summary and introduction.*

(1) Scope (suitable matrices) and source of method (e.g., "Manual of the Association of Official Analytical Chemists," or "EPA Manual of Chemical Methods and Devices" (see paragraphs (d)(1) and (d)(2) of this guideline).

(2) Principles of the analytical procedure (describe) including identification of the chemical species determined and the limits of detection and sensitivity.

(B) *Materials and methods.*

(1) Equipment (list and describe).

(2) Reagents and standards (list and describe source and preparation).

(3) Analytical procedure (detail in a stepwise fashion, with special emphasis on reagents or procedural steps requiring special precautions to avoid safety or health hazards):

(i) Preparation of sample.

- (ii) Extraction (demonstrate efficiency, if relevant).
- (iii) Clean-up.
- (iv) Derivatization (if any).
- (4) Instrumentation (to include information on):
 - (i) Description (e.g., make/model, type/specificity of detectors, columns, (packing materials, size), carrier gases, etc.).
 - (ii) Operating conditions (e.g., flow rates, temperatures, voltage, etc.).
 - (iii) Calibration procedures.
- (5) Interferences (describe tests):
 - (i) Sample matrices.
 - (ii) Other pesticides.
 - (iii) Solvents.
 - (iv) Labware.
- (6) Confirmatory techniques (describe).
- (7) Time required for analysis (to carry a sample/set completely through the analytical procedure, including the determinative step).
- (8) Modifications or potential problems, if any, in analytical methods (detail circumstances and corrective action to be taken).
- (9) Methods of calculation (describe in a stepwise fashion):
 - (i) Calibration factors.
 - (ii) Analyte in sample.
- (10) Other (any and all relevant information the petitioner considers appropriate and relevant to provide a complete and thorough description of residue analytical methodology and the means of calculating the residue results).
- (C) *Results and discussion* (describe expected performance of method).
 - (1) Accuracy (expected mean and range of recoveries).
 - (2) Precision.
 - (3) Limits of detection and quantification (provide definition).
 - (4) Ruggedness testing , if performed.

(5) Limitations.

(D) *Conclusions*. Discuss applicability of analytical procedure for measuring specific test compounds in various test substrates, ready availability of equipment, interferences, etc.

(E) *Certification*. Certification of authenticity by the study director (including signature, typed name, title, affiliation, address, telephone number, date).

(F) *Tables and figures*.

(G) *References*.

(H) *Appendices*.

(I) Representative chromatograms, spectra, etc. (as applicable).

(2) Other (any relevant material not fitting in any of the other sections to this report).

(2) [Reserved]

(d) **References**. The following references should be consulted for additional background material on this test guideline.

(1) *Manual of the Association of Official Analytical Chemists*, Association of Official Analytical Chemists (AOAC), Arlington, VA, latest edition.

(2) *EPA Manual of Chemical Methods and Devices*, published by Association of Official Analytical Chemists (AOAC), Arlington, VA (1992).